FemVue® Saline-Air Device

INSTRUCTIONS FOR USE

CAUTION-Federal (USA) law restricts the device to sale by or on the order of a physician.

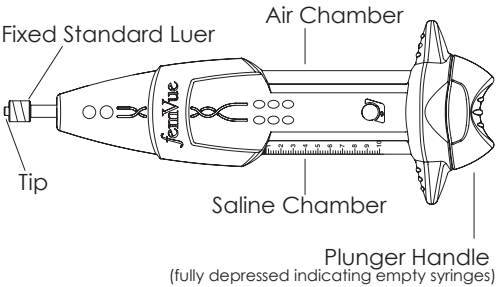
DEVICE DESCRIPTION

The FemVue Saline-Air Device (FemVue) is a dual-barrel contrast media syringe that can be connected to an intrauterine catheter to instill saline-air contrast medium as part of a sono-hysterosalpingogram (Sono HSG) procedure. Ultrasound evaluation of the fallopian tubes can be performed with or without assessment of the uterine cavity.

INDICATIONS FOR USE

The FemVue Saline-Air Device instills a consistent alternating pattern of saline and air as a continuous stream of contrast medium into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).

FEMVUE SALINE-AIR DEVICE



How Supplied
Sterile for single use only.

Storage
Store in a cool, dry place.

Required Ancillary Supplies
- Intrauterine catheter with balloon
- Sterile saline

CONTRAINDICATIONS

- Any condition that is a contraindication to hysterosalpingography.
- Current or recent pregnancy (previous 6 weeks) including miscarriage which may increase risk of air embolism.

WARNINGS / PRECAUTIONS

- Do not use oil-based contrast medium.
- To minimize risk of air embolism, do not exceed delivery of six (6) filled device volumes (max 60 mL of air) to the patient. Air embolism has not been reported in the literature with air volumes below 70 mL.
- FemVue should be performed after completion of the menstrual cycle and before the onset of ovulation.
- Single patient use only. Reuse creates a risk of infection.
- Do not use if sterile package is opened or damaged.

PROCEDURE PREPARATION

1. Perform pregnancy test when clinically indicated.
2. Have patient void.
3. Perform a bimanual exam to establish size, shape and position of the uterus. Rule out infection requiring treatment and deferral of procedure.

INSTRUCTIONS FOR USE

DEVICE PREPARATION

Ensure use of aseptic technique throughout procedure.

Prepare FemVue Device

a. Completely submerge device tip in sterile saline-filled bowl.

b. Fully pull back plunger handle and keep tip submerged until saline chamber is completely filled to the 10 mL mark, as confirmed visually.

Note: *FemVue fills with a delay. Keep tip submerged in saline during the entire filling process.*

ULTRASOUND PRE-SCAN

Baseline Assessment

a. Under transvaginal ultrasound guidance, locate the following in the transverse view:

- Endometrial stripe and cornua (**Figure 1**)
- Left and right adnexa
- Tubal course by scanning from each cornua to each adnexa (**Figure 2**)

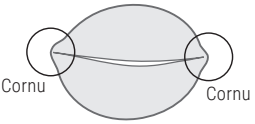


Figure 1

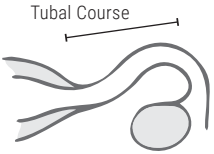


Figure 2

CATHETER PLACEMENT

Insert & Position Catheter

a. Insert speculum (side-open recommended) to visualize and cleanse cervix with an antiseptic solution.

b. Flush catheter prior to insertion with either saline, if conducting uterine cavity assessment first, or saline-air contrast (bubbles), if conducting tubal assessment only.

c. Insert catheter per Instructions for Use for the intrauterine catheter with balloon.

d. Inflate balloon and position above internal cervical os. Gently pull back catheter to ensure balloon is properly positioned to create a cervical seal and minimize backflow during procedure (**Figure 3**).

e. Remove speculum.

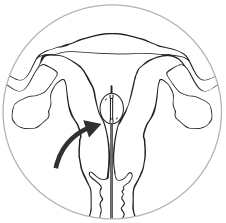


Figure 3

UTERINE CAVITY ASSESSMENT – SIS (optional)

Perform SIS

a. With a saline-filled syringe, perform uterine cavity evaluation per your practice guidelines.

Note: *SIS should be performed prior to tubal assessment since saline-air contrast may limit proper visualization of uterine cavity.*

b. After SIS, clamp catheter and detach saline syringe. Keep balloon inflated and maintain catheter position.

FALLOPIAN TUBE ASSESSMENT

Prime FemVue & Connect to Catheter

a. Prime previously filled FemVue by submerging tip in saline-filled bowl and depressing plunger handle until a bubble is visible.

Note: *Ensure FemVue is primed just before attachment to avoid delay in contrast visualization.*

b. Attach FemVue luer to catheter luer (**Figure 4**).

Note: *Do not overtighten FemVue's luer to catheter luer to ensure easy device disconnection for refilling.*

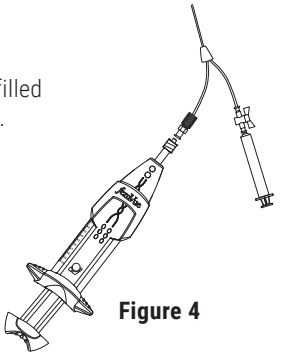


Figure 4

Deliver Contrast

a. Under sagittal view, slowly depress plunger handle to deliver saline-air contrast while maintaining traction on balloon catheter.

b. Confirm no backflow around balloon while visualizing bubbles entering the uterine cavity (**Figure 5**).

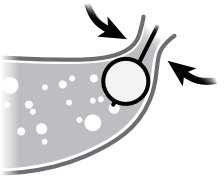


Figure 5

Complete Tubal Interpretation

a. Under transverse view, observe bubbles filling uterine cavity.

b. Focus on each cornu, tubal course and ovary to assess contrast flow, examining right and left side sequentially.

c. Tubal patency is confirmed with bubbles actively flowing into or through the tube OR exiting tube, around the ovary or in the cul-de-sac (**Figures 6-8**).

Note: *Probe must be held steady to observe and confirm bubbles flowing.*

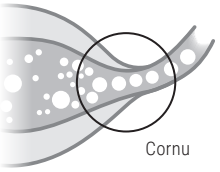


Figure 6

COMPLETE PROCEDURE

Remove Equipment

a. Remove ultrasound probe.

b. Deflate balloon per catheter's Instructions for Use and remove catheter.

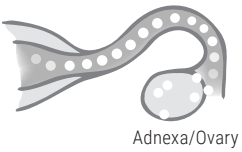


Figure 7

Disposal

a. Dispose of all products in accordance with all applicable Medical/Hazardous waste practices.

Patient Post-Care

a. Patient should expect leaking of fluid after the procedure that may be blood-tinged.

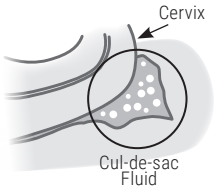


Figure 8

Refilling FemVue

a. Clamp intrauterine catheter
b. Disconnect FemVue from catheter
c. Fill FemVue
d. Prime FemVue
e. Reconnect FemVue to catheter
f. Unclamp catheter

Ensure bubbles are flowing from device into and through clear tube of catheter.

TROUBLESHOOTING

No contrast exiting catheter and plunger resistance is felt

a. Ensure catheter clamp is open.
b. Confirm catheter is not abutting tissue impeding flow.

No contrast flow visible into the tube

a. Ensure, in sagittal view, there is no backflow around balloon catheter. If backflow is observed, consider increasing balloon size or repositioning.
b. Consider repositioning ultrasound probe.
c. Hold probe, maintain plunger handle position, and wait to rule out possible tubal spasm.
d. Instill contrast slightly faster to increase pressure enabling flow into tube.
e. Consider change in patient's position: roll patient slightly onto left side to observe flow in right tube and vice versa.

SYMBOL LEGEND

REF	Reference number
LOT	Lot number
	Use by date
	Refer to Instructions for Use.
	Do not use if sterile package is opened or damaged.
2	Single Use
Rx Only	Federal (USA) law restricts the device to sale by or on the order of a physician.
STERILE EO	Sterilized using ethylene oxide

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